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DelMar Pharmaceuticals Presents Updated Phase I/II Clinical Data on VAL-083 in Refractory Glioblastoma Multiforme at GBM2015

- VAL-083 demonstrates dose-response and survival benefit in GBM patients failing standard front-line therapy and bevacizumab -

VANCOUVER, British Columbia and MENLO PARK, Calif., Sept. 10, 2015 /PRNewswire/ -- DelMar Pharmaceuticals, Inc. (OTCQX: DMPI) ("DelMar" and the "Company"), a biopharmaceutical company focused on the development and commercialization of new cancer therapies, today presented updated clinical data from its Phase I/II study of lead product candidate VAL-083 (*dianhydrogalactitol*), in patients with refractory glioblastoma multiforme (GBM), at GBM2015: 2nd International Symposium on Clinical and Basic Investigation in Glioblastoma in Toledo, Spain.

The Company's data was presented in a poster entitled,*"Update on Phase I/II study of VAL-083 (dianhydrogalactitol) in patients with recurrent malignant glioma."*

DelMar is conducting a multicenter Phase I/II clinical study with VAL-083 in patients with recurrent GBM. Eligible GBM patients must have failed both Avastin® (bevacizumab) and Temodar® (temozolomide) unless either of these therapies was contraindicated. (ClinicalTrials.gov Identifier NCT01478178). Data from the Phase I dose-escalation portion of the study was presented at ASCO. Dose limiting toxicity was observed at a dose of 50mg/m^2/day; no drug-related severe adverse events were reported and myelosuppression was mild at doses ≤40mg/m^2/day. Preliminary analysis suggested a dose-dependent and clinically meaningful survival benefit in GBM patients whose tumors had progressed following standard treatment with temozolomide, radiotherapy, bevacizumab and a range of salvage therapies.

"We view the trend toward a meaningful survival benefit, and at doses that were well tolerated by patients, as highly promising for the potential of VAL-083 to offer a new

treatment alternative for GBM patients. Our subsequent and more detailed analysis of data from the Phase I portion of this trial continues to support these observations," stated Jeffrey Bacha, DelMar's president and CEO.

The sub-group analysis for patients receiving up to 5 mg/m^2 daily x 3 every 21 days (low dose) versus those patients receiving 30mg/m^2 or 40mg/m^2 (high dose) was presented today at the GBM2015 meeting. In summary, the data indicated:

- Patients in the low dose sub-group had a median survival of 5 months versus median survival of 9 months for patients in the high dose sub-group following initiation of VAL-083 treatment ($p = 0.04$).
- Increased survival was observed at 6, 9 and 12 months following initiation of treatment in the high-dose sub-group compared to the low dose sub-group.
- Survival was not correlated with screening Karnofsky performance status ($R^2_{KPS} = 0.03$) or subject age at screening ($R^2_{AGE} = 0.01$).
- Survival was not correlated with the localization of either the initial or recurrent lesion.
- A longer time to progression following front-line temozolomide or second line bevacizumab treatment was not correlated with a survival benefit following initiation of VAL-083 therapy.
- All patients had failed standard treatments and one or more salvage therapies prior to initiation of VAL-083 (median number of prior therapies = 3 for both the low and high dose sub-groups). No commonalities in prior therapy were observed to correlate with survival.
- Survival was not correlated with MGMT expression in either the low dose or high dose sub-group.

"These analyses show a diminished possibility that factors, other than the proposed clinical activity of VAL-083, are responsible for the observed dose-dependent survival benefit following treatment," stated Mr. Bacha.

The Company has initiated a Phase II expansion cohort for the refractory GBM study at a dose of 40mg/m^2 with approximately 14 patients expected to be enrolled. The purpose of the Phase II expansion cohort is to gain additional information about the safety and efficacy of VAL-083 at the 40mg/m^2 dose prior to advancement into registration-directed Phase II/III clinical trials.

- To date, 20 patients have been screened and eight (8) patients have initiated treatment with VAL-083 at the 40mg/m^2 dose.
- To further explore the therapeutic window of VAL-083, three (3) patients have also initiated treatment at an interim dose of 45mg/m^2.
- The Phase II expansion cohort may be continued at the higher 45mg/m^2 dose if safety data warrants.

Further information on the trial design can be found on the company's website at http://www.delmarpharma.com/GBM_clinical_trial/

"We are pleased with the momentum of our enrollment in the trial. We look forward to presenting further data from the Phase II expansion study as we continue activities geared

toward the initiation of a registration-directed Phase II/III clinical trial over the course of the next several months," added Mr. Bacha.

The Company's poster presentation from GBM2015 may be found on DelMar's website under http://www.delmarpharma.com/products/publications/.

About VAL-083
VAL-083 is a "first-in-class," small-molecule chemotherapeutic. In more than 40 Phase I and II clinical studies sponsored by the U.S. National Cancer Institute, VAL-083 demonstrated safety and efficacy in treating a number of cancers including lung, brain, cervical, ovarian tumors and leukemia. VAL-083 is approved in China for the treatment of chronic myelogenous leukemia (CML) and lung cancer and has received orphan drug designation in Europe and the U.S. for the treatment of gliomas.

DelMar is currently studying VAL-083 in a multi-center Phase I/II clinical trial for patients with refractory GBM in accordance with the protocol that has been filed with the U.S. Food and Drug Administration (FDA) at five clinical centers in the United States: Mayo Clinic (Rochester, MN); UCSF (San Francisco, CA) and three centers associated with the Sarah Cannon Cancer Research Institute (Nashville, TN, Sarasota, FL and Denver, CO). As a potential treatment for glioblastoma, VAL-083's mechanism of action appears to be unaffected by the expression of MGMT, a DNA repair enzyme that is implicated in chemotherapy resistance and poor outcomes following front-line treatment with Temodar® (temozolomide).

About DelMar Pharmaceuticals, Inc.
DelMar Pharmaceuticals, Inc. was founded to develop and commercialize proven cancer therapies in new orphan drug indications where patients are failing or have become intolerable to modern targeted or biologic treatments. The Company's lead drug in development, VAL-083, is currently undergoing clinical trials in the U.S. as a potential treatment for refractory glioblastoma multiforme. VAL-083 has been extensively studied by U.S. National Cancer Institute, and is currently approved for the treatment of chronic myelogenous leukemia (CML) and lung cancer in China. Published pre-clinical and clinical data suggest that VAL-083 may be active against a range of tumor types via a novel mechanism of action that could provide improved treatment options for patients.

For further information, please visit http://delmarpharma.com/; or contact DelMar Pharmaceuticals Investor Relations: ir@delmarpharma.com / (604) 629-5989. Follow us on Twitter @DelMarPharma or Facebook.com/delmarpharma. Investor Relations Counsel: Amato & Partners LLC.

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Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. Any forward-looking statements contained herein are based on current expectations, but are subject to a number of risks and uncertainties. The factors that could cause actual future results to differ materially from current expectations include, but are not limited to, risks and uncertainties relating to the Company's ability to develop, market and sell products based on its technology; the expected benefits and efficacy of the Company's products and technology; the availability of substantial additional funding for the Company to continue its operations and to conduct research and development, clinical

studies and future product commercialization; and, the Company's business, research, product development, regulatory approval, marketing and distribution plans and strategies. These and other factors are identified and described in more detail in our filings with the SEC, including, our current reports on Form 8-K.

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To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/delmar-pharmaceuticals-presents-updated-phase-iii-clinical-data-on-val-083-in-refractory-glioblastoma-multiforme-at-gbm2015-300140458.html

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